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The study evaluates an intervention designed to facilitate treatment decision making, adjustment, and coping among early-stage prostate cancer patients and their spouse/partners, in a randomized controlled trial. The intervention is based on the Cognitive-Social Health Information Processing (C-SHIP) framework that postulates that decision making is determined by cognitive factors (i.e., perceptions about vulnerability; expectancies and beliefs; values and goals), affective factors (i.e., concerns and worry about the disease and its treatment), as well as self-regulatory skills (i.e., the ability to manage distress and effectively execute recommended behaviors). To date we have 249 couples enrolled in the study; 6 month follow-up questionnaires have been sent to 143 couples with 120 patients (84%) and 79 (55%) spouses/partners completed; 12-month follow-up questionnaires have been sent to 70 patients and 61 spouse/partners. We now have a total of 55 patients (79% return) and 41 spouse/partners (67% return) who have completed all of the required assessments for the study. Preliminary data analyses point to the acceptability and efficacy of the Cognitive and Affective Reactions and Expectations (CARE) intervention compared to the General Health Intervention, not only in the short-term but also in the long-term at 6-months post baseline.

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INTRODUCTION:

The study evaluates an intervention designed to facilitate treatment decision making, adjustment, and coping among early-stage prostate cancer patients and their spouse/partners, in a randomized controlled trial. The intervention is based on the Cognitive-Social Health Information Processing (C-SHIP) framework that postulates that decision making is determined by cognitive factors (i.e., perceptions about vulnerability; expectancies and beliefs; values and goals), affective factors (i.e., concerns and worry about the disease and its treatment), as well as self-regulatory skills (i.e., the ability to manage distress and effectively execute recommended behaviors). The goal of the Cognitive and Affective Reactions and Expectations (CARE) Intervention is to facilitate treatment decision making, by improving understanding of disease and treatment related facts, as well as by preparing the patient and his spouse/partner to anticipate the medical and psychological consequences of the disease and its treatment. This is being done in the context of a structured counseling session (approximate duration 45 min). Specifically, the patient's and spouse/partner's cognitive and emotional reactions to the following areas are explored: the treatment itself; potential side effects; long-term treatment success; relationship with others; and stress-management strategies. The efficacy of the intervention will be evaluated systematically with General Health Intervention (GHI) serving as a comparison condition, controlling for time and attention. In the GHI condition patients (and their spouse/partners) will receive and discuss current recommendations for general health (i.e., nutrition and stress management) and will explore their own attitudes, beliefs, and feelings on these topics with a health educator. Assessments will be obtained at baseline, and 6 weeks later, to assess treatment decisions, and at 6 months and 12 months post baseline to assess long-term adjustment and coping.

BODY:

RESEARCH ACCOMPLISHMENTS:

The following are tasks taken from the approved Statement of Work

Year 2: Task 3 and Task 4

(A) Continue participant accrual

We now have a total accrual of 387 couples for the study. Our completion rate is now 73% with 249 sessions completed (CARE 128;GHI 121) out of 340 (CARE 169; GHI 171) that were originally scheduled.

(B) Continue Assessments

Baselines questionnaires have been given to the 249 couples that completed a CARE or GHI session. We have received 179 baseline questionnaires (72%) from patients and 177 baselines (71%) from spouses/partners.

6-week follow-up questionnaires have been sent to a total of 19 patients who did not indicate a treatment decision in their baseline assessment. All 19 follow-ups have been received (100% return rate).

6 month follow-up questionnaires have been sent to 143 couples with 120 patients (84%) and 79 (55%) spouses/partners completed.

12- month follow-up questionnaires have been sent to 70 patients and 61 spouse/partners. We now have a total of 55 patients (79% return) and 41 spouse/partners (67% return) who have completed all of the required assessments (baseline, 6-month and 12-month) for the study.

(C) Check incoming data for accuracy – Enter data into database

We have continued to check incoming questionnaires for completeness and inclusion of questions or comments. Our research assistant then enters all questionnaires into the Oracle database.

(D) Continue Data Analyses

Over the past year we have started to conduct preliminary analyses on the questionnaire data.

- a) Data cleaning.** We examine all accumulated data for accurateness by performing range and logical checks. In addition, we perform spot checks on 10% of all entered questionnaires to catch data entry mistakes. To date our data has been entered with 99% accuracy.
- b) Scale construction.** Measures of negative affect, (i.e., POMS), CES-D depression, intrusion and avoidance (i.e., revised impact of event scale; RIES) and quality of life (QOL; FACT-P) have been constructed by combining the appropriate items into scales. The reliability values of these scales are uniformly high: POMS positive affect ($\alpha = .89$); POMS negative affect ($\alpha = .92$); CESD depression ($\alpha = .78$); RIES intrusion ($\alpha = .89$); RIES avoidance ($\alpha = .80$). For the FACT-P and its subscales we have obtained acceptable reliability values: FACT-P physical well being subscale ($\alpha = .73$); FACT-P social well-being subscales ($\alpha = .69$); FACT-P emotional well-being subscale ($\alpha = .73$); functional well-being ($\alpha = .89$); FACT-P prostate-specific additional concerns ($\alpha = .77$). We have not found any differences by intervention/comparison group on any these scales, suggesting that the randomization procedure has been successful.
- c) Description of sample.** Patients are eligible to participate if they have been diagnosed with localized carcinoma of the prostate, and have not made a treatment decision. As of to date, we have received 179 baseline questionnaires (72%) from patients and 177 baselines (71%) from spouses/partners (total $N = 356$). Ninety percent of our sample is Caucasian, 7% is African American, and 1% is Hispanic. Half of the sample (51%) have at least a high school education, 28% completed college, and 21% have a post-graduate degree. More than half of the patients are retired (53%), 43% are employed, and 4.5% are either disabled, unemployed, or semi-retired. Patients are on average 64.5 years old.
- d) Evaluation of Intervention sessions.** Upon agreeing to participate into the study, couples were randomized into the CARE or the GHI condition. Preliminary analyses of data assessing the acceptability and usefulness of these sessions suggest that both of the sessions are well accepted. For the CARE intervention, 60% of patients indicated that the session was quite a bit or very useful to understand potential side-effects of prostate cancer treatment; 67% indicated that there was enough information to make a treatment decision; 74% thought the information about side-effects was above average, good, or excellent; 73% indicated that the discussion about treatment consequences was above

average, good, or excellent; and 72% thought it provided a good or excellent forum to hear the partner's treatment opinions. Most importantly, almost 70% of patients indicated that the information provided was useful for treatment decision making, that the information was very understandable (94%), and that the focus on patients' values and goals during the session was very important (73%). Overall, 41% rated the sessions as excellent, 36% as good; 6% as above average (the remaining 17% rated the sessions as average or poor (2.1%)).

The GHI session that focused on nutritional needs during prostate cancer treatment was equally well accepted. Patients indicated that the session was quite a bit or very helpful to understand the potential link between nutrition and prostate cancer (54%), and that it quite a bit or very much addressed concerns about nutrition (64%). Patients rated the nutritional information we provided with respect to specific treatment options very highly: for surgery (52% good to excellent); external beam radiation (60% good to excellent). Overall, 21% rated the sessions as excellent, 41% as good; 15% as above average (the remaining 20% rated the sessions as average or poor (2.6%)).

e) Efficacy of intervention. Based on preliminary analyses of the baseline data there were no differences by study group with regard to worry and distress about, and satisfaction with one's treatment decision. The only difference that emerged by study group was that patients in the CARE group indicated the treatment decision to be somewhat more difficult compared to patients in the GHI group. This is not surprising, given the nature of the CARE intervention, which by reviewing all treatment related issues and connecting those issues to personal goals and values, might have momentarily made the decision somewhat more difficult. We interpret this result as an indication that patients processed the relevant information and that increased perceived difficulty is the "cost" of such processing. When examining this variable at the 6-month assessment point, this difference disappears, further reinforcing that this was a temporal effect.

We next examined the long-term effects of the CARE/GHI sessions on the treatment decision variables using data collected at the 6-mo assessment point. There were no differences with regard to worry about treatment decision and distress about the decision. When asked, however, if they would make the same treatment decision again, patients in the CARE condition were significantly more likely to indicate that they would choose the same treatment again compared to patients randomized to the GHI condition. In addition,

patients in the GHI condition indicated significantly greater levels of regret about their treatment decision compared to men in the CARE condition. These are preliminary results on small samples and should be evaluated with caution, however, they point to the efficacy of the intervention.

OTHER ACCOMPLISHMENTS –YEAR 2:

To increase our retention rate, we remind all couples about the importance of returning the questionnaires through phone calls as well as postcards. We have also developed a newsletter to keep couples informed about the study while also providing them with the latest information about prostate cancer and treatments. The newsletter also serves as reminder to return the assessments.

We have also incorporated the nursing staff into our retention effort by asking them to remind patients that they are scheduled to meet with us after their physician consultations. We have also provided couples with a pager number to contact us when they arrive for their appointments. This has proven to be valuable in helping us locate patients when they arrive at FCCC and eliminating confusion about their scheduled session.

KEY RESEARCH ACCOMPLISHMENTS:

- Continuation of baseline and 6-month assessments
- Successful return rates for patient and spouse baselines
- Development of a informative newsletter for the participants to stimulate retention
- Favorable participant recruitment
- Initiation of the 12-month assessment
- Incorporation of the nursing staff in maintaining retention of participants
- Initial analyses support the efficacy of the CARE intervention

REPORTABLE OUTCOMES:

a) Publications:

Diefenbach, M.A., Dorsey, J., Uzzo, R.G., Hanks, G.E., Greenberg, R.E., Horwitz, E., Newton, F., Engstrom, P.F. (2002). Decision making strategies for patients with localized prostate cancer. Seminars in Urologic Oncology

b) Conference Presentations:

Diefenbach, M.A., Dorsey, J., Hanks, G.E., Greenberg, R.E., Horowitz, E., Uzzo, R., Engstrom, P.F., Newton, F., Schlager, B., Lanciano, R. (2002, April).

Information Seeking by Prostate Cancer Patients and Information Provided by their Physicians, 23rd Annual Meeting of the Society of Behavioral Medicine, Washington, DC.

Diefenbach, M.A., Dorsey, J., Knauer, C., Hanks, G., Greenberg, R., Horowitz, E., Uzzo, R., Engstrom, P. (2002, March). Information Preferences and Information Seeking among Prostate Cancer Patients. The 26th Annual Meeting of the American Society of Preventive Oncology, Bethesda, MD.

CONCLUSIONS:

We have made progress in the recruitment of eligible patients and their spouses/partners, and have conducted 249 CARE and GHI sessions. Questionnaires are processed, entered in the database, verified, and cleaned. We have continued to conduct preliminary data analysis and have found some promising results that underscore the efficacy of our intervention. To achieve our recruitment goal for the study, we will continue with recruitment, conduct of intervention sessions and perform data analysis.

REFERENCES: None

APPENDICES: None